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FORMULATION AND EVALUATION OF PIROXICAM DISPERSABLE TABLET BY DIRECT COMPRESSION METHOD

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ABSTRACT

Piroxicam has been the most widely used Non steroidal anti-Inflammatory drug for many decades. The present investigation concerns the development and evaluation of dispersible tablets of Piroxicam which after oral administration are designed to easily disintegrate and dissolve thus improving the bio-availability. The dispersible drug delivery system was developed using Sodium Starch glycolate and crospovidine as disintegrating agents. The prepared tablets are evaluated in terms of their physical characteristics *in vitro* release, uniformity of dispersion test, wetting time, determination of moisture content by Kf Apparatus. The results showed that the optimized formulation (F_3) showed the disintegration time of 29 sec, percentage drug release of 99% at the end of 15 minutes which satisfied all the tablet evaluation parameters for dispersible tablet. Hence the tablet formulations found to be economical and easy to manufacture in large scale due.

KEY WORDS: Piroxicam dispersible tablets, Non-steroidal Anti inflammatory drugs, Wetting Time.

1. INTRODUCTION

The oral route of drug administration is the most important method of administering drug for systemic effects.90% of all drugs used to provide systemic effect are administered by oral route (Jinying, 2004). Tablet is defined as solid pharmaceutical dosage form containing drug substance with or with out suitable diluents and prepared by either compression or molding method. Tablet remains popular as a dosage form because of the advantage afforded both to the manufacturer (e.g.simplicity and economy of preparation, stability, and convenience in packing, shipping and dispensing) and patient (e.g. accuracy of dosage, compactness, portability, blandness of taste, and ease of administration) (Birju,2009). Although tablets frequently are discoid in shape, they also may be round, oval oblong, cylinder or triangular. They may differ greatly in size and weight depending on the amount of the drug substance present and the intended method of administration.Compressed tablets usually are prepared by large-scale while molded tablets generally involve small-scale operation. Most recently, new concept and federal regulations being made on bioavailability and bioequivalence and on validation are impacting on tablet formulation, design and manufacture. Pharmaceutical products are processed all over the world using the direct compressing, wet granulation, or dry granulation method.Method is chosen depend on the ingredients individual characteristics like flow property, compressibility. Direct compression is generally done for the crystalline material (Milind,2010). Wet granulation is widely used and most general method of tablet preparation. The wet granulation technique is done by adding a solute, suspension or slurry containing binder this can be aqueous or non aqueous which is added to the dry mix powder. The main advantage is it meets the requirements of tablet formulation and main disadvantage is it requires many steps in process, which is time consuming (Anupama,2009). Dry granulation type of process is recommended for products, which are sensitive to moisture and heat.Dry granulation can be done on a tablet press slugging tooling (Sandeep,2010). The main advantage of granulation is it requires less equipment and eliminates the addition of moisture and the application of heat. Dispersible tablet are uncoated tablet that produce a uniform dispersion in water in three minutes that passes through mesh No.22. The chief advantage is quicker absorption and onset of clinical effects. They are generally prepared for geriatric or pediatric patients or those who are having difficulty in swallowing tablets. They dissolve in mouth within 1 minute, using some in 10 seconds (Jashanjit Sing and Rajmeet singh,2008). No need or little water is required to swallow the dosage form which is highly convenient feature for patients who are traveling and do not have access to water. Rapid disintegration of the tablet and absorption of drug tends to produce quick onset of action.Quick absorption from the gastro intestinal tract improves bio availability and reduces unwanted effect caused by the drug (eg:Gastro-intestinal irritation). The disadvantage is most fast disintegrating tablet lack the mechanical strength common to traditional tablet (Mallikarjuna,2008). Many products are very lightweight and fragile requiring them to be individually packaged. Piroxicam is a non-steroidal anti-inflammatory drug of the oxicam class used to relieve the

symptoms of rheumatoid and osteoarthritis, primary dysmenorrhoea, postoperative pain, and act as an analgesic, especially where there is an inflammatory component (Birju,2009).

2. MATERIALS AND METHODS

Piroxicam was received as a gift sample from SIGNET Corporation. Micro crystalline cellulose was obtained from Colorcon Asia Pvt. Ltd., Lactose was obtained from DMV International, Starch was obtained from M/s. Ridhi Sidhi Chemicals, Sodium starch glycolate and Crosprovidone was obtained from Arvind Laboratories, Chennai., Aspartame was obtained from Trident Pharmaceutical Pvt. Ltd., Magnesium Stearate state, Talc were procured from Dow Chemicals, Methanol (HPLC Grade) was obtained from Ranbaxy Chemicals Ltd., Karl Fisher Titrating Solutions was procured from Severna Scientific Ltd., All other ingredients, reagents and solvents were of analytical grade.

2.1 Formulation of dispersible tablets: The tablets were prepared by direct compression method by using 8/32 BC oval FFBE punches and with a break line on one side. Piroxicam were sifted through 24 mesh, microcrystalline powder sifted through 40 mesh. Other ingredients sifted through 60 mesh. The above ingredients were blended in double cone blender for 25 mins & lubrication was carried out for 5 min. The lubricated blend was compressed by using oval FFBE 9.5 punches (Jashanjit,2008).

2.2 EVALUATION

2.2.1Determination of Micromeritic properties of the granules (Zade,2009)**:** The micrometric properties of the prepared granules has been evaluated by suitable method and the result has been tabulated in table 2.

2.2.2 Physical evaluation of tablets: The following physical evaluation parameters such as appearance test, dimension, weight variation, hardness, friability, disintegration, uniformity of dispersion, moisture content by KF test, drug content and wetting time and the results were tabulated in table 3(Parmar,2004).

2.2.3 *In-Vitro* Drug release studies: These studies of formulated tablets was carried out using USP dissolution apparatus type-II (paddle), at 50 rpm, at 37 ± 5^0 C in 900 ml of phosphate buffer (pH 7.4) as dissolution medium. The sample was taken for every 3 min and the drug content was estimated by UV method at 254 nm (Furtado, 2008).

Table 1 Formulation of piroxicam dispersible tablet

S.No	Ingredients (mg)	F1	F2	F3	F4	F5	F6
1	Piroxicam	20	20	20	20	20	20
2	Micro crystalline cellulose	10	15	20	10	15	20
3	Sodium starch glycolate	5	10	15	-	-	-
4	Crospovidone	-	-	-	5	10	15
5	Aerosil	5	5	5	5	5	5
6	Starch	25	25	25	25	25	25
7	Aspartame	5	5	5	5	5	5
8	Pineapple flavor	2	2	2	2	2	2
9	Magnesium stearate	5	5	5	5	5	5
10	Lactose	21	11	1	21	11	1
11	Talc	2	2	2	2	2	2
	Total	100	100	100	100	100	100

3. RESULT AND DISCUSSION

3.1 Micromeritic properties of the Piroxicam dispersible tablets: The Bulk density of various powder mixed blends prepared with different super-disintegrants, was measured by graduated cylinder. The bulk density was found in the range 0.41-0.43 kg/cm^3. The Tapped density of various powder mixed blends prepared with different super disintegrants, was measured by graduated cylinder. The Tapped density was found in the range 0.45-0.48 gm/cm^3. The Compressibility index of various powder mixed blends, prepared with different super disintegrants, using bulk density and tapped density data, compressibility index was calculated. It was found in the range 8.27-10.60%. The Hausner's ratio of various powder mixed blends, prepared with different super disintegrants, using bulk density and tapped density data, Hausner's ratio was calculated. It was found in the range 1.0 to 1.1.

3.2 Physical evaluation of tablets: Tablets were prepared using direct compression technique. Since the material was free flowing, tablets were obtained of uniform weight due to uniform die fill tablets were obtained in the range with acceptable weight variations as per pharmacopoeia specifications, less than 5%.

Tablets were evaluated by using Vernier calliper. The thickness of the tablets was found in the range 2.6± 0.1mm. Uniformity thickness was obtained due to uniform die fill. Tablets were evaluated by using Pfizer Hardness tester. Hardness of the tablets was found in the range 3.42–3.71 Kg/cm^2. Uniform hardness was obtained due to equal compression force. Tablets were evaluated by using Roche Friabilator and friability of tablets was observed in the range 0.291-0.428. Tablets were evaluated by using assay method. The drug was obtained in the acceptable limit. The drug content was found in the range 98.3–102.7. Tablets were evaluated for disintegration time in the IP disintegration apparatus. The disintegration time was found in the range 29–35 sec. Tablets were evaluated for wetting time test. The wetting time was found in the range 54–59 sec.

3.3 Moisture content of the piroxicam dispersible tablet: The result of the moisture content of the formulated piroxicam dispersible tablets were studied and the result has been tabulated in table 3.

3.4 Assay of piroxicam dispersible tablet: The results of the assay of piroxicam were done as per procedure 5.10 and presented in the table 3.

3.5 *In-Vitro* Drug release studies: These studies were conducted for the formulations using USP dissolution apparatus type-II(paddle),at 50 rpm.The % drug release at the end of 15 min was found in the range 85-99 %.

4. CONCLUSION

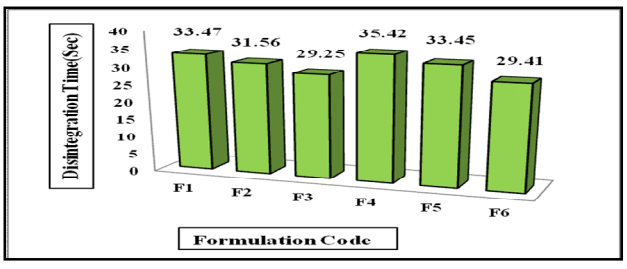
In the present study, the formulation of piroxicam dispersible tablets is an attempt to select best possible combination of diluents and disintegrants. Starch used as binder, aspartame as a sweetening agent, Magnesium stearate and Talc as a Lubricant, Aerosil as a Glidant. The percentage Drug content of all the formulation was found to be between 98.3 to 102.7%, which is within the limit. The post compression parameters like Hardness, Friability, Disintegration time, weight variation, wetting time, Dispersion time values were found to be within the IP limits. All the formulations were showed the acceptable flow properties and the pre-compression parameters like Bulk density, Tapped density and Hausner ratio. The formulation F3 showed disintegration time of 29 seconds followed by percentage drug release of 99% at the end of 15 min which satisfied all the tablets evaluation parameters for dispersible tablet.

Table 2 Micromeritic properties of the Piroxicam dispersible tablets

Code	Bulk density(gm/cm^3)	Tapped density(gm/cm^3)	CompressibilityIndex (%)	Hausner's Ratio
F1	0.425	0.464	8.60	1.094
F2	0.416	0.459	9.36	1.103
F3	0.425	0.465	8.60	1.094
F4	0.421	0.459	8.27	1.090
F5	0.425	0.470	9.57	1.105
F6	0.430	0.481	10.60	1.118

Table 3 Physical evaluation of tablets

Formulation Code	F1	F2	F3	F4	F5	F6
Moisture content (%w/w)	2.1	2.2	1.8	2.2	2.3	1.9
Assay of piroxicam in % w/w	98.3	98.6	99.0	102.7	102.5	101.2
Wetting time(sec)	54.54	54.54	54.54	54.54	54.54	54.54
Thickness (mm)	5.7	5.7	5.7	5.7	5.7	5.7
Hardness (Kg/cm^2)	3.50	3.50	3.50	3.50	3.50	3.50
Friability (%)	0.293	0.293	0.293	0.293	0.293	0.293
Disintegration time (sec)	33.47	33.47	33.47	33.47	33.47	33.47
Uniformity of dispersion	Pass	Pass	Pass	Pass	Pass	Pass



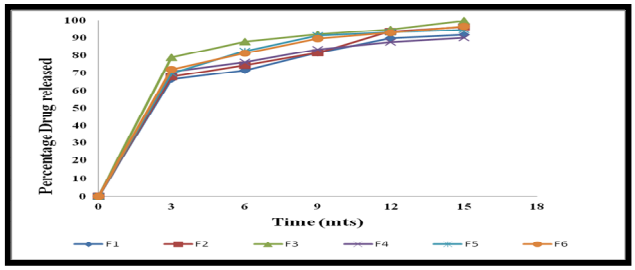


Figure 1&2 Disintegration time and *In-vitro* Drug release studies of piroxicam dispersible tablet

Table 4 Comparative Dissolution Profile of Piroxicam dispersible tablets in pH7.4 Buffer Solution

Time (min)	Cumulative percentage drug release					
	F1	F2	F3	F4	F5	F6
3	66.42	67.89	79.00	70.74	69.77	72.07
6	71.69	74.49	87.91	76.24	82.59	81.36
9	81.72	81.66	92.14	83.62	91.48	89.00
12	89.83	93.89	95.13	87.78	93.40	93.23
15	91.82	96.60	99.18	90.12	94.90	96.87

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